.

QUALITY ASSURANCE MANAGEMENT PLAN

FOR

THE SUPERFUND DIVISION

APRIL 2002

QUALITY ASSURANCE MANAGEMENT PLAN
for
THE SUPERFUND DIVISION

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ACRONYMS AND ABBREVIATIONS

ADQ	Audit of Data Quality
ADP	Automatic Data Processing
ANSI/ASQC	American National Standard/American Society for Quality Control
AR	Administrative Record
ASTM	American Standards for Testing Materials
BCRLF	Brownfield Cleanup Revolving Loan Fund
BEAS	Brownfield and Early Action Section
CBI	Confidential Business Information
CEPP	Chemical Emergency Preparedness and Prevention
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Register
CO	Contracting Officer
CRL	Central Regional Laboratory (Region 5)
CS	Contract Specialist
DCN	Document Control Number
DCO	Document Control Officer
DQA	Data Quality Assessment
DQAMP	Divisional Quality Assurance Management Plan (Superfund)
DQO	Data Quality Objectives
ERB	Emergency Response Branch
ERRS	Emergency Rapid Response Services
EMSL	Environmental Monitoring System Laboratory (ORD)
EPA	Environmental Protection Agency
ESS	Enforcement Support Services
FAR	Federal Acquisition Regulations
FSS	Field Services Section
GIS	Geographical Information System
GSA	General Services Administration
ITS	Information Technology Section
IGCE	Independent Government Cost Estimate
MARLAP	Multi-Agency Radiation Laboratory Protocol Manual
MSR	Management System Review
NARA	National Archives and Record Administration
NCP	National Continency Plan
NPL	National Priority List
OSC	On-Scene Coordinator
OPA	Oil Pollution Act
PE	Performance Evaluation
P&A	Precision and Accuracy
PC-DOC	PC Division/Office Coordinator
PM	Project Manager
PMB	Program Management Branch
PMIS	Program Management and Information Section
PO	Project Officer
PRP	Potentially Responsible Parties
QA	Quality Assurance
QAMP	Quality Assurance Management Plan (Region 5)
QAPP	Quality Assurance Project Plan
QC	Quality Control
QASPER	Quality Assurance Sampling Plan for Environmental Response
QAARWP	Quality Assurance Annual Report and Work Plan
QMP	Quality Management Plan
RAC	Remedial Action Contract
ROC	Regional Oversight Contract
RRB	Remedial Response Branch
RPM	Remedial Project Manager
RQAC	Regional Quality Assurance Core

RQAM	Regional Quality Assurance Manager
RQAT	Regional Quality Assurance Team
SARA	Superfund Amendments and Reauthorization Act
SCAP	Superfund Comprehensive Accomplishment Plan
SFD	Superfund Division
SIRMO	Servicing Information Resources Management Officer
SOP	Standard Operating Procedure
SOW	Statement of Work
START	Superfund Technical Assessment & Response Team
TM	Task Monitor
TQM	Total Quality Management
TSA	Technical System Audit
VCP	Voluntary Cleanup Program
WAM	Work Assignment Manager
WP	Work Plan

INTRODUCTION

The U.S Environmental Protection Agency (U.S. EPA) Order 5360.1 A2 (Policy and Program Requirements for the Mandatory Agency-Wide Quality System, May 2000) requires participation in a centrally managed Quality System by all EPA organizational units and by organizations performing work in behalf of EPA through extramural agreements. Components of this system are illustrated in Figure 1. The intent is to develop a unified approach to Quality Assurance (QA) to ensure the collection of data which are scientifically sound, legally defensible and of known and documented quality. The Divisional Quality Assurance Management Plan (DQAMP) is submitted to the Regional Quality Assurance Manager (RQAM) for review/approval. The DQAMP is a management tool appropriately tailored to the needs of Superfund Division (SFD), defining how its QA program objectives are attained.

It is a document that reflects the ways in which QA activities are currently performed. The DQAMP will be reviewed at least annually and revised or updated as necessary by the Superfund Division Quality Assurance Team Leader. All the changes will be submitted to the RQAM for inclusion in the Quality Assurance Annual Report and Work Plan (QAARWP).

1.0 MANAGEMENT AND ORGANIZATION

The Superfund Division, under the management of the Director, is responsible for implementing the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Superfund Amendments and Reauthorization Act (SARA) and the Oil Pollution Act of 1990 (OPA). The SFD integrates QA in managing the development, coordination, implementation and evaluation of all technical, enforcement and administrative support aspects of the Superfund Program within the Region, including emergency response and removal activities, the SARA Title III Program, remedial and enforcement activities at Superfund sites, State cooperative agreements, information and record management, technical analysis and support, and contracts management. The Superfund Division is also responsible for working with the States local emergency planning committees, and tribes in Region 5 along with other Federal Agencies in developing multi-media Chemical Emergency Preparedness and Prevention (CEPP) contingency plans and related activities.

The SFD is organized into the Immediate Office (IO) and four branches, and the Office of Chemical Emergency Preparedness and Prevention (OCEPP). The Branches are as follows:

Emergency Response Branch (ERB)
Program Management Branch (PMB)
Remedial Response Branch No.1 (RRB1)
Remedial Response Branch No.2 (RRB2)

The Emergency Response Branch (ERB) is responsible for Regional/area wide contingency planning and response to emergency removal actions at uncontrolled hazardous waste sites and oil spills under the provisions of the National Contingency Plan (NCP), CERCLA and OPA. The Branch directs the development, coordination and implementation of the Early Action Process and Brownfields Initiatives.

The Remedial Response Branches (RRBs) are responsible for planning, managing and implementing a program for investigation and clean-up, through remedial and/or enforcement action, at the highest priority uncontrolled hazardous waste sites within the six-State Region. The Branches direct the development, coordination and implementation of the remedial investigation/ feasibility study process, the overall remedial design and construction process, Federal facilities coordination, study environmental justice coordination, and potentially Responsible Party (PRP) searches, and cost recovery activities

The Program Management Branch (PMB) is responsible for providing administrative support to both the removal and remedial programs. The Branch manages remedial contracts, the CERCLIS and WasteLAN databases, the Record Center, Freedom of Information Act (FOIA) requests, and outyear planning and accomplishment reporting. The Field Services Section (FSS) in PMB provides technical support to the removal and remedial programs by conducting geophysical surveys and collection of soil and groundwater samples. The Divisional Quality Team Leader and Quality Assurance staff are located in FSS. The QA staff reviews and approves Quality Assurance Project Plans (QAPPs), Quality Management Plans (QMPs), and provides training to the SFD on QA issues.

1.1 Divisional Quality Assurance Policy

Divisional Quality Assurance Policy will follow the Regional policy(Sections 2.1, 2.2, and 2.3 of RQAMP) by ensuring that:

♢ All work performed by or on behalf of the SFD that involves the collection and use of environmental data will be implemented in accordance with an approved QAPP.

♢ The initial review of all remedial program and brownfield projects QAPPs will be provided by a QAPP reviewer in FSS.

♢ The approval of QAPPs at staff level will be provided by a QAPP reviewer from the FSS, by qualified Remedial Project Manager (RPM) or On Scene Coordinator (OSC), after the document being initially reviewed by a QAPP reviewer.

♢ All environmental data generated by or for the SFD will be of known and documented quality, as defined by pre-established Data Quality Objectives (DQOs). In general, the DQOs process should be performed as part of the planning and development of a QAPP for specific data collection.

♢ All the QA criteria for all SFD projects and tasks are documented in the SFD operating guidance.

♢ An adequate degree of assessment will be performed on the SFD projects to determine compliance with QA requirements.

♢ The project deficiencies are highlighted and corrective actions are appropriately taken.

♢ All activities that effect the quality of data within the divisional responsibilities will be performed by appropriately trained staff.

♢ QA training will be provided to staff at all levels to ensure that QA requirements and responsibilities are understood and implemented at all stages of the project.

1.2 Quality Assurance Responsibilities

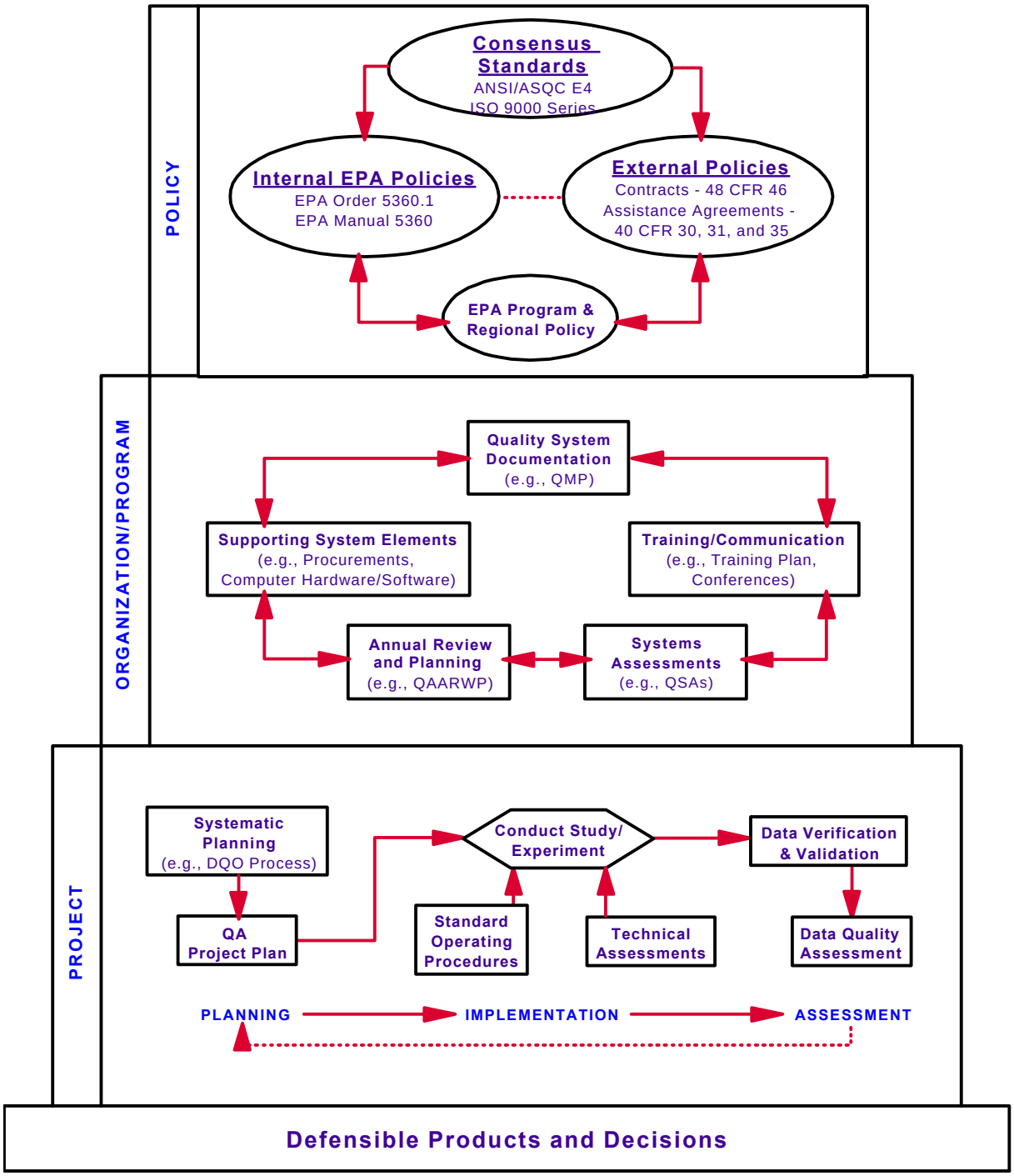
This section defines the SFD structure and management methodology within which Quality Assurance is planned and implemented, with a clear delineation of the responsibility and authority of the personnel and organization involved. The SFD has an identifiable QA program through the establishment of Quality Assurance Team Leader who is located in Program Management Branch, Field Services Section. The QA Team Leader is assisted by QA staff throughout the Division. The Superfund Division organizational chart is shown in Figure 2.

Responsibilities of QA staff

QA personnel are staffed in three sections. This includes six chemists in the FSS, one chemist in the Federal Facilities Section (FFS), and one health physicist in the Emergency Response Section #3. QA personnel are responsible, as appropriate, for:

- ♢ Logging in the QAPPs (the SOP for QAPP log-in can be found in Attachment A).
- ♢ Provide the information about status of each document review to the QA Team Leader.
- ♢ Maintain the files and records pertaining to QAPP/Data Validation reviews, including the QA Document Tracking System and the quarterly reports providing the status of documents submitted for the review to FSS. An example of a quarterly report is included in Attachment A.
- ♢ Review and approve QAPPs, to ensure that all data collection activities are covered by appropriate documentation.
- ♢ Attend and lead the project scoping/pre-QAPP meetings to ensure that Agency and Regional QA policies are addressed.
- ♢ Conduct data evaluation for achievement of DQOs.
- ♢ Conduct laboratory audits for compliance with the DQO for the project.
- ♢ Oversee and audit Environment Science Assistant Team (ESAT) data review packages for technical and contractual completeness and accuracy based on current Statement of Works (SOWs) or Standard Operating Procedures (SOPs) for PRP-Lead Projects and recommend an evaluation of ESAT to the Regional Project Officer.

Figure 1. EPA Quality System Components and Tools (EPA QA/R-2)



◊ Conduct on-site audits of field activities for consistency with QA objectives and appropriate QA procedures including Contract Laboratory Program (CLP) requirements.

- ♢ Conduct audits of CLP and non-CLP lab for technical and contractual compliance, including on-site visits.
- ♢ Provide training on data review to the data user.
- ♢ Assist SFD staff in determining whether statistical assistance is required.
- ♢ Provide assistance to SFD staff, when requested, to perform DQA of the project.
- ♢ Provide QA training to states/tribes and SFD staff.

Quality Assurance Team Leader Responsibilities

Divisional QA Team Leader is responsible for QA oversight, ensuring that all personnel understand divisional QAMP and their QA/QC responsibilities. Per EPA QA Order 5360.1 A2, Section 7.d, the QA Team Leader's functions and responsibilities include:

- ♢ Maintain active communication with the RQAM and Regional Quality Assurance Core (RQAT) group.
- ♢ Maintain active participation in Regional QA Team (RQAT) chaired by RQAM.
- ♢ Participate in the Agency and Regional workgroups.
- ♢ Assist management in developing the divisional QAMP.
- ♢ Review the DQAMP at least annually and revise or update as necessary, and distribute the revised DQAMP for implementation.
- ♢ Ensure that all field and office personnel involved in environmental data collection receive training or information needed to become knowledgeable in QA requirements, protocols, and technology.
- ♢ Ensure that all environmental data collection activities are covered by appropriate QA planning process and documentation (i.e., DQOs and QAPPs).
- ♢ Coordinate/assist in resolving QA-related issues/problems within the Division.
- ♢ Consult with RQAC on complicated QA issues.
- ♢ Ensure that audits/reviews are conducted to ensure that environmental data collection activity adheres to the approved QAPPs and to identify deficiencies in QA/QC systems.

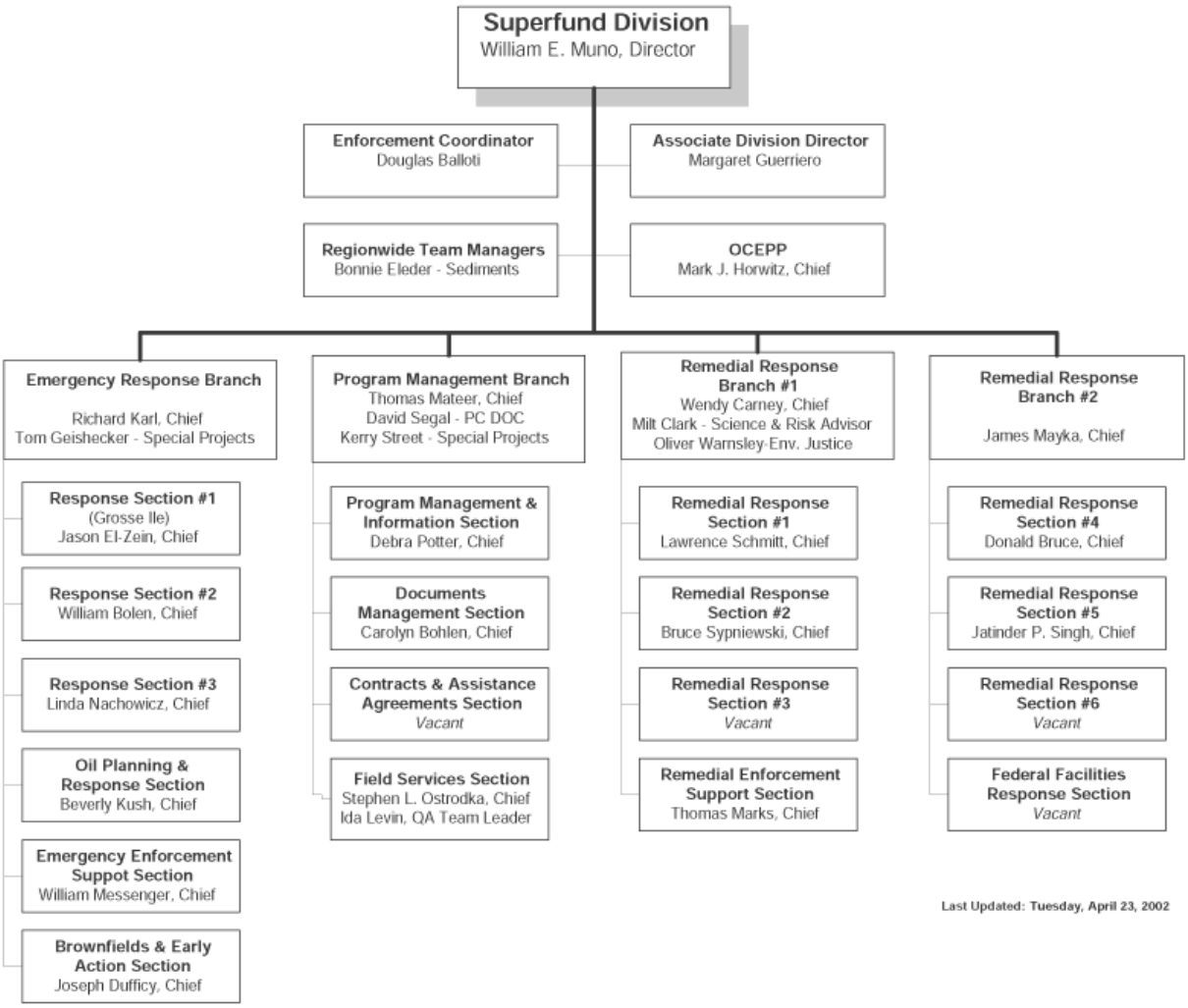


Figure 2. Superfund Division Organizational Chart

- ♢ Ensure adequate corrective actions are taken/implemented in response to audit/review findings.
- ♢ Recommend the required management-level corrective actions to the SFD Director.
- ♢ Initiate and conduct, with concurrence of the SFD director, the internal QA management system review (MSR) of at least one program element per year.
- ♢ Provide guidance on the Quality Assurance Management System to State/Tribe, review of the state/tribe QAMPs, and provide technical assistance to the state/tribe on revisions as necessary.
- ♢ Identify QA/QC training needs for the organization.
- ♢ Provide QA training to states/tribes and SFD staff.
- ♢ Track SFD QA activities (i.e., documents {QMPs, QAPPs, SOPs, etc.} review/ approval, inspections, audits, program management review {e.g., MSR}, and QA training).
- ♢ Prepare and submit to the RQAM the Quality Assurance Annual Report and Work Plan (QAARWP).
- ♢ Review and approve State/Indian Tribe QMPs.
- ♢ Review contractors' QMPs.
- ♢ Assist SFD staff in determining whether statistical assistance is required.
- ♢ Provide assistance to SFD staff, when requested, to perform DQA of the project.
- ♢ Participate with RQAT in the conducting MSRs of Region 5 Divisions and State/Tribal quality systems.
- ♢ Assist Regional Team Managers to ensure that the same Regional QA requirements are met by environmental activities performed by, or on behalf of the team.
- ♢ Develop a library of pertinent QA documentation to assist technical staff.

SFD Staff responsibilities

SFD staff personnel is responsible for implementation of the QA program. Per the EPA QA Order 5360.1 A2 , Section 7.e, staffs' major responsibilities are:

- ♢ Ensure that all applicable intramural programs and activities comply fully with the requirements of the EPA QA Order.
- ♢ Ensure that all applicable extramural environmental programs and activities for which they are responsible, including those which are performed by organizations other than EPA, comply with the EPA QA Order.
- ♢ Ensure that the results of the environmental programs are of sufficient quantity and adequate quality for their intended use.
- ♢ Identify their QA training needs to management and QA Team Leader.

♢ Ensure that they understand the specific QA/QC requirements for their environmental data collection.

♢ Conduct peer review activities as determined appropriate by the Division Director.

SFD Managers Responsibilities

SFD management is responsible for overseeing the implementation of the Quality Assurance (QA) program. Per the draft EPA QA Order 5360.1 A2 , Section 7.e, managers' major responsibilities are:

♢ Ensure that the SFD QAMP is distributed and properly implemented.

♢ Ensure that quality management is an identified activity with associated resources adequate to accomplish its program quality goals.

♢ Ensure that all subordinate organizational components and programs are fully compliant with the requirements of the QA Order.

♢ Ensure that all applicable environmental programs for which management is responsible and which are performed by outside organizations for EPA comply fully with the requirements of the QA Order.

♢ Assure that the results of the environmental programs are of sufficient quantity and adequate quality for their intended use.

♢ Section chiefs have to ensure that RPMs, PMs, and OSCs seeking QAPP approval authority receive mandated QA training.

SFD Director's Responsibilities

The Director has overall responsibility for managing the Divisional QA program according to Agency QA policy and the Region's QA Program specifications. The Director has final authority of approving QA policy and documentation at the program office level.

In accordance with the EPA Order 5360.1 A2 , Section 7.c, the Division Director's responsibilities are:

♢ Ensure that a QAMP for the SFD is in place and implemented; on an annual basis, the QAMP is properly reviewed/evaluated for its effectiveness to the program, and revisions made, as needed, in a timely fashion.

♢ Ensure that any changes to the QAMP for the program are distributed to RQAC, and all personnel performing work for the program, including all program staff, active contractors, teams sponsored, and financial assistance recipients.

♢ Ensure that each organization performing work for the program, including all active contractors has an approved QAMP for that specific organization implemented.

♢ Ensure that QA policies are established and QA requirements are reflected in internal and external program guidance, monitoring budgets, program plans and operating plans.

♢ Ensure that QAPPs are developed for each applicable monitoring project and are properly reviewed and approved prior to initiation of the project.

- ♢ Ensure that the DQO process and established acceptance criteria are used for monitoring projects.
- ♢ Oversee that appropriate corrective actions resulted from either internal or external audits are taken.
- ♢ Ensure that program-specific QA training needs are identified and provided.
- ♢ Ensure that guidance on the preparation of the Quality Assurance Management System to state/tribe government is provided, and that a QAMP is in place and properly implemented.
- ♢ Ensure that the same Regional QA requirements are met by the state/tribe governments.
- ♢ Ensure that the SFD QAPP review/approval process is established and the QAPP approval authority is designated.
- ♢ Ensure QA and QC training needs for all level of management and staff is provided.
- ♢ Ensure that performance plans for supervisors, senior managers, and appropriate staffs contain a critical element that is commensurate with the quality management responsibilities assigned by the Order and SFD QAMP.
- ♢ Ensure that Federal agencies and state, local and tribal governments performing environmental data collection activities for EPA are provided training in the fundamental concepts and practices of quality management and QA/QC that they may be expect to perform.
- ♢ Ensure that QA resources are adequate to achieve Regional and program goals.
- ♢ Ensure that peer review is conducted and documented as appropriate.

2.0 QUALITY SYSTEM COMPONENTS

The complexity of environmental data operations demands that a systematic process and structure be established to provide decision makers with the necessary confidence in the quality of data produced for the decision to be made, as well as with the means to determine when the data are not fully usable and what to do about the situation. Detailed QA procedures and measurement system are documented in the following sections.

2.1 QAMP Preparation Responsibilities, Approval and Review

The Superfund Division is complying with the EPA Order 5360.1 A2, which requires a QAMP to be the blueprint for planning, implementing, and evaluating a QA program for the environmental work to be performed. This requirement applies to the Division as well as any active contractors and financial assistance recipients involved in environmental data gathering.

2.1.1 Superfund Division QAMP

The QA Team Leader is responsible for preparing the divisional QAMP to cover all environmental activities within the division. The QA Team Leader distributes the QAMP to Branch Chiefs for review/comment, and incorporating comments received. The Divisional QAMP will be internally approved by Branch Chiefs and the Director, and subsequently reviewed and approved by the Regional Quality Assurance Manager (RQAM) and the Regional Administrator.

The approval is valid for five years, and may be subject to revision depending on organizational and/or policy/process changes within the respective Division/Office, and findings from the management system reviews.

The QA Team Leader will review the QAMP on an annual basis. Major revisions will be made if it is apparent that the QAMP does not truly reflects the QA processes in any function area. Other eventualities such as inadequate or prescriptive policies and procedures that are inappropriate for the needs of the division may also lead to revisions.

2.1.2 State Agency QMPs

Each State Agency which performs work for, or is funded through a multi-year grant/financial assistance by Region 5, shall have an approved QMP implemented for use by all staff of the State Agency. This QMP document provides information on how the State Agency's management will plan, implement and assess its Quality System to meet the Regional QA policy and QA requirements for the Superfund Program. The State Agency senior management is responsible for the development and implementation of its QMP, and for distributing its QMP to all personnel performing work for the given State Agency.

The State Agencies must have Quality System in place before performing any work for the EPA. The Superfund Division retains authority to approve all Quality Assurance Project Plans (QAPPs) for any Superfund activities. QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

2.1.3 Indian Tribal QMPs

There are no current requirements for Indian Tribes to submit the QMPs for Superfund projects. The process will be described in details, when it becomes part of the Superfund program.

2.1.4 Contractors QMPs

Each contractor who performs work involving environmental data operation activities for/or is funded by Region 5, shall have an approved contractor's QMP which is required for awarding the contract. The contractors' QMP provides information on how the contractor's management will plan, implement, and assess its Quality System to meet the Regional QA policy and QA requirements for the Superfund Division. The contractor senior management is responsible for the development and implementation of its QMP, and for distributing it to all personnel performing work for the contractor.

The contractor's QMPs are prepared by the contractor and submitted for the review/approval to U.S. EPA. The QMPs will be prepared according to the "EPA Requirements for Quality Management Plans " EPA QA/R-2, March 2001. The Divisional QA Team Leader, the Project Officer (PO) and Contracting Officer (CO) review the submitted QMPs. The PO and CO are responsible for approving the QMPs.

2.1.5 Potentially Responsible Party Contractors' QMPs

Each contractor who performs work involving environmental data operation activities for a Potentially Responsible Party (PRP) under an enforcement order shall have an approved QMP. The contractors' QMP provides information on how the contractor's management will plan, implement, and assess its Quality System that complies with ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and

Environmental Technology Programs."

The contractor's QMPs are prepared by the contractor and submitted for the review/approval to U.S. EPA. The QMPs will be prepared according to the "EPA Requirements for Quality Management Plans " EPA QA/R-2, March 2001, or equivalent documentation. The site RPM or OSC is responsible for the review and approval of the QMP with input from FSS QA reviewers.

2.2 Systematic Planning or Data Quality Objectives (DQOs) Process.

Environmental monitoring and measurement programs conducted by or for the Superfund Division are designed to produce technically and legally defensible data of a quality sufficient to support its intended use. The SFD policy is to implement the DQO process for all projects, as appropriate, involved in the environmental data collection.

The DQO process is a systematic planning tool to facilitate the planning of environmental data collection activities. DQOs are qualitative and quantitative statements developed from the DQO process. The DQOs process is a seven-step planning approach used to prepare for data collection activities. It provides a systematic approach for defining the criteria that a data collection design should satisfy, including when, where, and how to collect samples; tolerable decision error rates; and the number of samples to collect. The DQO process helps investigators ensure that the data collected are of the right type, quantity, and quality needed to support environmental decision.

The seven steps of the DQO process are:

- ♢ State the Problem
- ♢ Identify the Decision
- ♢ Identify Inputs to the Decision
- ♢ Define the Study Boundaries
- ♢ Develop a Decision Rule
- ♢ Specify Limits on Decision Errors
- ♢ Optimize the Design for Obtaining Data

The DQO process will define qualitative and quantitative criteria for determining when, where and how many samples (measurements) to collect for a desired level of confidence. The information along with sampling procedures, analytical procedures and appropriate QA/QC procedures will be documented in the QAPP. The following documents are used for the development of the DQO process for Superfund sites: "Data Quality Objectives Process for Superfund" EPA 540-R-93-071, September 1993, "Data Quality Objectives Process for Hazardous Waste Site Investigations" EPA QA/G-4HW, January 2000, and "Guidance for the Data Quality Objectives Process " EPA QA/G-4, August 2000.

2.3 Quality Assurance Project Plans (QAPPs)

All work performed by or for USEPA Region 5 that involves the collection and use of environmental data will be done according to an Agency approved QAPP. The QAPP documents how environmental data collection operations are planned, implemented, and assessed during the life cycle of a project or task. The purpose of the QAPP is to define in details how quality assurance and quality control activities will be implemented for a particular project. The following documents are used for the development of QAPPs for Superfund sites: "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations" EPA QA/R-5, March 2001, "EPA Guidance for the Quality Assurance Plans" EPA QA/G-5, February 1998, and Region 5 Instructions on the Preparation of a Superfund Division QAPP.

Both the Remedial and Removal programs of the SFD collect and manage environmental data.

Each program has a distinct administrative process for QAPP preparation, review and approval. The following sections describe the QA responsibilities of various personnel within each program and process used to ensure that the program collects and manages data at quality levels commensurate with regulatory and policy needs.

The data collection activities of Removal Branch may be subject to the time constraints and specialized goals of an Emergency response effort. While the goals of the Remedial Program are focused on investigation and complete remediation of long-term environmental health threats, the focus of the Removal Program is on stabilization, containment, and removal of immediate health and safety threats. It is not a goal of the Removal Program to affect final cleanups. Therefore, the data collection activities of the Removal Program differ in focus from the Remedial Program.

2.3.1 Remedial Program

QAPP Preparation

The QAPP will be prepared by different parties depending on the project lead designation. QAPP for sites that are Potentially Responsible Party (PRP) lead will be prepared by the PRP or their contractor, and will require U.S. EPA Region 5's approval. QAPPs for Fund lead projects will be prepared by U.S. EPA Region 5 or state agency contractors or by the Remedial Project Manager (RPM).

Despite the project lead designation, all QAPPs should have a scoping/pre-QAPP meeting organized by the site RPM to include all parties involved in the project. This will include, as appropriate, the PRP, contractor, analytical laboratories, and state agency and USEPA Region 5 support staff of chemists, toxicologists, ecologists, geologists, engineers, safety specialists, statisticians, etc. During this meeting, participants will discuss project description, data quality objectives for the project (see section 2.2), intended data usage, sampling procedures, safety issues, parameters to be tested for each sample type, analytical methods selected to achieve the project objectives and data usage, the need of laboratory performance and system audits, data validation, and data quality assessment. The documentation necessary for the QAPP preparation should be provided during the meeting.

The RPM will prepare a summary memo of the meeting and distribute it to meeting participants and place a copy in the project file.

QAPP Review

After the scoping/pre-QAPP meeting, a comprehensive QAPP shall be prepared according to Region 5 Instructions on the Preparation of a Superfund Division QAPP. A QAPP package shall be submitted to USEPA Region 5 for review and approval. A complete QAPP package shall include a copy of the QAPP, the sampling plan and the work plan.

Upon receipt of the QAPP package, the RPM will conduct a preliminary screening of the QAPP, using Region 5 Superfund QAPP Check List, included in Attachment B of Region 5 Instructions on the Preparation of a Superfund Division QAPP. The preliminary screening ensures that the QAPP contains the necessary QAPP elements and meets project objectives as was discussed during the scoping/pre-QAPP meeting. If the initial draft does not contain the necessary QAPP elements, it is returned to the preparer for corrections. Otherwise, the complete QAPP package along with a QAPP review request form, (Attachment A), is submitted to FSS for review and comment. The form should provide the following information: Site Name, Site ID, Action Code, Operable Unit, State, Lead (PRP, Fund, State), RPM's name and phone number, and a requested completion date. RPMs are responsible for identifying the laboratories specified in the QAPP.

Upon receipt by FSS, each document is logged in and given a FSS number. The QA Team Leader will assign a reviewer for the project. If the project involves sampling/analysis for

radioactive material, the document will also be assigned to the health physicist located in the Emergency Response Section # 3 for the review and comments. If the date requested for the completion of a QAPP review cannot be met, the FSS Chief will meet with the appropriate Remedial Branch Chief to discuss priority setting.

If the QAPP is not approvable, the FSS reviewer and/or health physicist reviewer will identify specific deficiencies and provide specific recommendations for corrections. The comments will be sent to RPM. Otherwise, the FSS reviewer will recommend it for approval.

QAPP Approval

Upon receipt of QAPP comments, the RPM will review the comments to see if further clarifications with the reviewers (FSS reviewer or health physicist) before transmitting to the QAPP preparer are necessary. When clarification is necessary, the RPM will first discuss the comments with the FSS reviewer and then transmit the comments to the QAPP preparer.

A meeting or conference call with appropriate parties involved in QAPP preparation process may be held prior to revising the document. Such meeting or conference call can be held upon suggestion of the RPM or request of the QAPP preparer.

The RPM will review the revised QAPP submitted by the QAPP preparer. The QAPP revision should consist of, when practical, only those pages revised. Revised pages must be marked per document control format.

The RPM will approve the revised QAPP (if they are qualified) or send it back to FSS for review and approval. The RPM is qualified to approve a QAPP if they have attended the Superfund Division training for QAPP review and approval, and have the appropriate education and/or experience with quality assurance and analytical procedures.

If the RPM approves the QAPP after revision, the notification of the approved QAPP must be submitted to FSS.

If FSS approves the QAPP, the approval memo will be sent to RPM.

The completed signature page should be submitted to FSS after all signatures are collected. The dates on the signature page will be the entered as QAPP approval date in FSS data files.

The information from the QAPP review request form along with the QAPP approval date is entered into a computer data base maintained by FSS. All SFD supervisors have access to the data base to be able to check on status of QAPP approval. The SFD sample coordinator can also check to ensure that an approved QAPP is in place prior to scheduling fund lead project samples for analysis.

2.3.2 Removal Program

There are three types of removal actions: emergency, time critical and non-time critical. In the case of classic emergencies, such as spill responses, immediate action is required to protect human health and the environment. Time critical removal actions are defined as those which must be initiated within six months. Non time critical actions are those defined as action that take more than six months to plan and initiate.

A contract-wide QAPP is prepared by each contractor used by the Emergency Response Branch

(ERB) for emergency response and removal action work. Each QAPP is reviewed by the QA staff and approved upon contract award. These QAPPs cover the broad range of work that is routinely performed under the Emergency Rapid Response Service (ERRS) and Superfund Technical Assessment & Response Team (START) contracts. In case of classic emergencies, because of the nature of emergency response and removal action work, a site specific sampling plan is not usually prepared prior to the commencement of field work. These sampling plans will meet the requirements of the situation, and therefore may not be in the same format of time critical sampling plans. The sampling plans are prepared within 45 days after completion of the emergency removal. All other cases, where work will be done by EPA contractors, require the preparation of the site-specific Sampling and Analysis Plan (SAP), which outlines site specific sampling and analytical procedures for the project. The minimum requirements for the SAP can be found in Attachment A. The OSC for each site determines what sampling is necessary in the field during the removal action or removal site assessment, at which time the contractor prepares site-specific SAP according to the approved procedures in the QAPP. The site-specific SAP with the completed signature page should be submitted to FSS.

There are rare instances when a contractor other than ERRS or START is used for a large removal project. In these instances, a site-specific QAPP following the Region 5 Instructions on the Preparation of a Superfund Division QAPP, June 2000, will be prepared by the contractor. These QAPPs will be sent to QA staff for review, and the OSC, if qualified to approve QAPPs, may approve the revised QAPP. If the OSC approves the QAPP after revision, the notification of the approved QAPP must be submitted to FSS. If the OSC is not qualified to approve the QAPP, it will be approved by the QA staff. If FSS approves the QAPP, the approval memo will be sent to the OSC. The completed signature page should be submitted to FSS after all signatures are collected. The dates on the signature page will be the entered as QAPP approval date in FSS data files.

The information from the QAPP review request form along with the QAPP approval date is entered into a computer data base maintained by FSS. All SFD supervisors have access to the data base to be able to check on status of QAPP approval.

Site assessment work is also performed by Region 5 states and Remedial Action Contract (RAC) contractors. A generic QAPP has been developed by each of these separate entities, and has been approved. Site assessment work performed by the START contractor will be conducted under the START generic QAPP. Site specific sampling plans are prepared for each site sampled by the state and RAC contractors.

2.3.3 Brownfields, Site Assessment and Early Actions

2.3.3.1 Brownfield Assessments

Much of the work conducted in the Brownfields Program involves site assessment activities, often ASTM Phase I and Phase II analyses conducted by states, municipalities and other political subdivisions and/or their consultants. The Office of Special Projects Staff in OSWER has produced QA/QC guidelines for Brownfield assessment activities which will serve as a starting point for these site characterization actions.

For federally-funded assessments performed by states, the Superfund Division will rely on the non-site specific Site Assessment QAPPs and their amendments the states developed originally for traditional Superfund Site Assessment activities. No site-specific QAPPs will be developed. However, sampling plans will be developed for each brownfield assessment and sent to the Region for comments by Brownfield and Early Action Section (BEAS) staff no less than 10 days

prior to sampling.

For federally funded assessments performed by municipalities as part of the Brownfield Pilot Program, scoping meetings will be held to determine the best technical approach for the site, including QA issues. These meetings will include representatives from the municipality, state, BEAS assigned staff and FSS as necessary. Pilot specific QAPPs will be developed utilizing Region 5 Instructions on the Preparation of a Superfund Division QAPP, state voluntary cleanup program (VCP) guidelines and HQ elements as appropriate. Site specific sampling plans will be developed for Pilots with multiple property assessments. QAPPs will be approved by QA staff and qualified PMs. Sampling plans will be approved by BEAS staff. All documents will become part of the official Pilot/Project file. Privately financed assessment activities will follow appropriate state VCP QA protocols and will be reviewed and approved by BEAS and appropriate state staff.

2.3.3.2 Brownfield Cleanup Revolving Loan Fund Actions

The Brownfield Cleanup Revolving Loan Fund (BCRLF) pilot grants authorize state and local government recipients to issue low interest loans to private parties for brownfield site cleanups utilizing CERCLA trust funds. These actions must meet the Removal Program criteria for non-time critical response. As such, each grant recipient, in conjunction with US EPA, will name a lead agency and OSC who will assume the roles and responsibilities outlined in the National Contingency Plan (NCP) at 40 CFR 300.415. QAPP preparation and review will follow the SFD's process for the Removal Program in section 2.3.2 of this document. The ERRS and START contracts will not be utilized in the cleanups of the Brownfield sites. BEAS staff will work with each local government grantee to help assure that loan recipients are aware of all QA/QC requirements.

2.3.3.3 Traditional Site Assessment and Early Actions

Site Assessment activities (pre-National Priority List {NPL} site characterizations) are performed by Region 5 states and START contractors. Generic QAPPs have been developed by states for these entities. These QAPPs will be modified to reflect changes in mission as necessary. Site specific sampling plans are prepared for each site investigated and reviewed by BEAS staff.

Early Actions (investigations and removals performed at sites in the NPL scoring queue) are conducted by Agency contractors and/or responsible parties under the direction of a PM/OSC designated by the SFD/state. Site specific QAPPs are developed for each response. QAPP reviews and approvals follow the procedures outlined under Sections 2.3.1 and 2.3.2 of this document.

2.4 Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) are documented protocols for performing routine or repetitive tasks related to some segment of the environmental monitoring activity. In Region 5, the QAPP is the essential documentation for all monitoring tasks. However, an office that has responsibility for a segment of the monitoring task may have SOPs. SOP or a segment of SOP (e.g., laboratory analytical procedure, procedure for sample collection, etc.) that is related to the element of the QAPP may be referenced in the QAPP. The QAPP may contain the SOP or that segment of the SOP as an appendix that relates to the task covered if SOPs are not on file. The SOP will be reviewed by the respective program QA staff along with the QAPP for approval/ disapproval. The primary guidance document for the preparation of SOPs is "Guidance for the Preparation of Standard Operating Procedure" EPA QA/G-6.

An organization (Regional Program Offices, State Agencies, Indian Tribal Governments, and local governments), which is responsible for a series of continuous routine environmental monitoring tasks may prepare a QAPP to cover all these activities, which the QA staff will review and approve. In this instance, a QAPP will include a series of SOPs used for these continuous environmental monitoring activities. Revisions are made per regulatory or programmatic changes, and should be approved by the SFD QA staff.

The attached Region 5 Instructions on the Preparation of a Superfund Division Quality Assurance Project Plan (Section B 4) lists all laboratories' SOP required elements for non-CLP analytical methodologies.

SOPs for sample collection should include, at a minimum, the following elements:

- ♢ Scope and Application
- ♢ Method Summary
- ♢ Definitions
- ♢ Sampling Equipment/Apparatus
- ♢ Safety
- ♢ Sample Containers and QC Procedures
- ♢ Preservatives
- ♢ Procedures
- ♢ QA/QC and Chain-of-Custody
- ♢ Documentation and Reporting
- ♢ Waste minimization and handling
- ♢ References

SOPs for other purpose should include, at a minimum, the following elements:

- ♢ Scope and Application
- ♢ Equipments and Resources
- ♢ Procedures
- ♢ Documentation and Reporting
- ♢ QA/QC requirements if applicable
- ♢ References

2.5 Technical Assessment

An assessment is a formal evaluation of performance to predetermined standards, and documentation of audit results to affect change toward improved performance, and include the technical system audit and performance evaluation:

Technical System Audit (TSA) is a thorough, systematic on-site qualitative inspection of facilities, equipment, personnel, training, procedures, record-keeping, quality control practice and data validation, data management, and reporting aspects of a system. ***The technical system audit applies to both laboratory audit and field inspection.***

The technical system audits are performed before the data collection activities to verify the existence, and to evaluate the adequacy of equipment, facilities, supplies, personnel, and procedures documented in the QAPPs. Additional system audits (e.g., field audits of sample collections, laboratory analysis, etc.) may be conducted during the data collection activity as needed.

Technical system audits will be requested by the Project Managers at the time the draft QAPP for the project has been developed and written, and will be scheduled by the respective QA Team Leader. The audit request will include information such as the nature of the project, the project needs (e.g., the type of monitoring activity, monitoring parameters, procedures to be used, etc.). The QAPP serves as the benchmark for the audit. The audit check list will be used for field and laboratory audits.

A performance evaluation (PE) is defined as the incorporation of a calibrated device traceable to a known reference standard (i.e., use of samples of known composition and concentration) randomly into the measurement system to check the analytical procedure. These samples are used to control and evaluate the accuracy and precision of the measurement systems, and to determine whether QA objectives of the project have been met. These (PE) samples can be introduced into the measurement system as single blind (the composition is known, but concentration is not) or as double blind (both composition and concentration are unknown).

The RPM shall make the request, through the Superfund QA staff**,** for a performance evaluation when the draft QAPP for the project has been developed and written. The performance evaluation request will identify the monitoring parameters, analytical methods/procedures to be used, the required detection limits, and the facility (i.e., name and address of the laboratory) that will provide the analytical services. Performance evaluation of the laboratory for approval/ disapproval will be performed before the initiation of the data collection activity. The QAPP will serve as the benchmark for survey officer to decide what evaluation materials are to be used. The frequency of evaluation will be determined based on the needs, past experience with a particular sampling and analysis procedures, or past performance of a particular laboratory.

2.6 Data Quality Assessment (DQA)

Data Quality Assessment (DQA) process includes both the qualitative review of the project to determine if project-specific QA/QC practices are followed and project objectives are achieved, and the statistical analysis of data to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. A complete or partial DQA can be performed during the assessment phase of data life cycle, which includes the planning, the implementation and the assessment phases. DQA is used to determine if the planning objectives were achieved. During the DQA, the data are first validated and verified to ensure that the sampling and analysis protocols specified in the QAPP were followed, and that measurement systems performed in accordance with the criteria specified in the QAPP, and then proceed to using the validated data set to determine if the quality of the data is satisfactory.

The DQA process is built on the fundamental premise that "Data Quality" is meaningful only in context of the intended use of data, by the decision maker. The results of DQA should be used for two specific purposes. First, for the specific decision, it can be used in making recommendations to the decision maker to modify portions of the DQAs. Secondly, it can be used as a guide for the planning and acquisition of supplemental data for this project and potentially for other related projects. RPMs/OSCs are responsible for DQA activities.

The DQA process involves three major areas that begin with a review of the planning documentation and end with the answer to the question posed during the planning phase of the study:

1. **Project implementation**: Evaluate the field activities (COC; number of samples collected and QC samples collected; method used for collection; holding times', etc.) and laboratory analysis (parameters reported; holding times; etc.).

2. **Conformance to approved performance criteria**: Evaluate the field and laboratory data through reviewing the data sets to determine the conformance to the requirements specified in the approved QAPPs. RPMs/OSCs are responsible for initiating the data review/validation request to the respective program QA personnel. Data will be assessed in terms of it's: precision, accuracy, representativeness, completeness, comparability (PARCC).

   The Superfund QA staff will perform Data Validation following the "US EPA Contract Laboratory Program National Functional Guidelines for Organic Data Review" EPA 540/R-94/012, February 1999; "US EPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review" EPA 540/R-94/013, February 1994 or QAPP approved Data Validation Guidance to determine the conformance to the technical and quality specifications for all the measurements that described in approved QAPP, and provide written reports to the RPMs/OSCs.

   At this time there is not a similar program in place, like the CLP, to assess the quality of radioanalytic data. Superfund QA staff performs Data Validation of radioanalytic data and procedures with the following documents:
   1) "Eastern Environmental Radiation Facility Radiochemistry Procedures Manual," EPA 520/5-84-006, August 1984;
   2) "Radiochemical Analytical Procedures for Analysis of Environmental Samples," EPA 1979;
   3) " Environmental Measurement Laboratory Procedures Manual," DOE HASL-300-Ed.27;
   4) "Radiochemical Data Verification and Validation" Draft April 7, 1995 (developed through intersite participation through the Radiochemical Data Verification and Validation Workgroup with EPA, DOE, DOD and the private sector); and
   5) "Laboratory Data Validation Guidelines for Evaluating Radionuclide Analysis, SAIC", September, 1992.
   Currently, there is a multi-agency workgroup whose primary focus is to develop a federal guidance document which will provide a framework to ensure that laboratory data will meet the specified data quality objectives. This document is called the "Multi-Agency Radiation Laboratory Protocols Manual" or MARLAP. When MARLAP is final, it will be the sole document used to assess radioanalytic data.

3. **Achievement of project objectives:** Evaluates whether the specific objectives are met; the overall project objectives are met; regulatory decision can be made; data support original DQOs.

DQAs will be conducted and used on the project by project basis. DQA's guidance titled "Guidance for Data Quality Assessment", EPA QA/G-9, 2000 and "Data Quality Evaluation Statistical Tools", EPA QA/G-9D, 1996 (or DataQUEST software program) should be used as a guide.

3.0 PERSONNEL QUALIFICATION AND TRAINING

EPA policy requires that personnel performing work on environmental programs shall be qualified to perform assigned work including and according to any project-specific requirements. Normal EPA hiring practices specify hiring based upon qualifications specified at the time of recruitment. However, during an employee's career, job requirements change and additional training may become necessary.

The application of sound QA policies and procedures requires that all staff, including RPMs, OSCs, field personnel, and data processors who generate or use environmental data are provided with the appropriate level of QA training commensurate with their duties.

First-line supervisors are responsible for ensuring that each employee with QA related assignment has the necessary qualifications and proficiency for the work assigned. It is a responsibility of line management to discuss QA training needs with personnel involved in environmentally related data gathering activities during the midyear and annual performance evaluation process.

A QA training requirement should appear within the standards of the QA Team Leader and other staff, as appropriate. For example, RPMs and WAMs are responsible for ensuring that all contract personnel involved with the gathering environmental data have the necessary QA training for their tasks and functions. Training priorities should be scheduled with management approval.

Line management is ultimately responsible for the quality of data. Therefore, it is critical that first-line managers and supervisors receive the necessary training to ensure their understanding of the importance of QA, their responsibilities as line managers of environmental data collection activities, and specific QA policies and procedures. Training is accomplished by attending seminars developed by Regional Quality Assurance Training workgroup.

In-house training to RPMs, OSCs, states and tribes will be provided by SFD QA personnel annually on the Region 5 Instructions on the Preparation of a Superfund Division Quality Assurance Project Plan and as appropriate for new updates in QA policies and procedures.

The RPMs/OSCs are qualified to approve a QAPP if they have attended the Superfund Division training for QAPP review and approval, and have the appropriate education and/or experience with quality assurance and analytical procedures.

The Quality Assurance Team Leader will develop a library of pertinent QA documentation to assist technical staff.

The QA staff will participate in all Regional QA training as appropriate. The QA staff will attend national QA meetings.

Other programmatic and technical/safety training is necessary for Superfund Division staff to satisfactorily perform their jobs. Health and safety training is required for personnel who engage in field activities by EPA Order 1440.2 and consists of an initial 40 hours of training together with annual 8-hour refreshers. RPMs and OSCs are required to attend appropriate courses offered by the CERCLA Education Center (i.e., Fundamentals of Superfund, Remedial Process, Removal Process, Enforcement Process, Federal Facilities Remediation, and Innovative Treatment Technologies). Project Officers, Work Assignment Managers, and Delivery Order Officers are required to take contract administration training and periodic recertification. Courses offered by the Environmental Response Training Program are recommended as appropriate. One course highly recommended is the Sampling for Hazardous Material (165.9). This course is designed to be consistent with the EPA protocol and guidance document Data Quality Objectives for Remedial Response Action.

4.0 PROCUREMENT OF ITEMS AND SERVICES

SFD must ensure that the items and services it procures are procured with EPA regulations, delivered in a timely fashion, and are within the required specifications. The following sections

will provide general guidance on SFD procurement procedures. Due to the changes to 48CFR, new pre award and post award QA review forms are required for all work assignments under existing contracts and for all new issued contracts. The forms are included in Attachment A. The QA review forms are prepared and approved by the contract project officer, the QA Team Leader, and the work assignment manager, as appropriate.

4.1 Procurement of Items

SFD utilizes the services of EPA Region 5 Acquisition Section of the Acquisition and Assistance Branch for most procurement of items. This Section follows the guidelines developed in the Federal Acquisition Regulations (FAR) section 13 which establishes government-wide policies and procedures governing the acquisition process. The "EPA 1900 Contract Management Manual" has been developed to supplement the FAR. Region 5 is required to implement the regulations in these documents. EPA attempts to purchase through FAR mandatory sources (i.e., GSA). Therefore, items on the FAR sources list that meet the minimum specifications on the procurement request (EPA Form 1900-8) must be purchased through a FAR source. Procurement of computer hardware and software contain somewhat different regulations. Computer procurement will be developed with assistance of the Information Technology Section (ITS) and adhere to Region 5 policy.

All procurements are documented using the procurement request form (EPA Form 1900-8). Instructions are included with the form. A purchasing agent will inform the originator of the item that most closely matches his/her request that is available from the FAR mandatory sources. Manufactures names and models are helpful if the description is incomplete. This does not mean that the brand name will be ordered. A purchasing agent may complete a purchase on "brand name or equals" specifications. If the item available from the mandatory source does not meet specifications, and no substitute is adequate, a purchasing agent will help the originator process a Waiver Request. However, if the items total price are less than $2,000 and the type of items are not available through mandatory sources, the purchasing agent may buy from the suggested source.

Procurement request forms will be reviewed by the supervisor for completeness and accuracy and routed through SFD required approvals. Funds are certified as available by the Budget and Finance Section which assigns a document control number (DCN). The procurement request is then sent to the Property Management Officer and to other Resources Management Division personnel (e.g., safety officer, librarian, etc.) as appropriate for approval. It is then sent to the Acquisition Section for action.

Item receipt and tracking of receivables are very important, since EPA is required under the Prompt Payment Act to pay vendors 30 days after receipt of the invoice or the item, whichever is later. Procured items are delivered to the EPA Region 5 warehouse or the Superfund warehouse in Willowbrook. The warehouse receiving clerks distribute the items to the person designated in the procurement request form. Upon delivery, the clerk will ask the receiver to sign a receiving form which the clerk then sends to Finance for vendor payment. All equipment is inspected at the time of receipt to identify defects or inoperativeness.

Selected SFD staff may also procure low cost (up to $2500) items utilizing a government bankcard. These individuals have received the necessary training and authorization to receive a delegation of procurement authority. Inspection of the items purchased is made upon receipt of the items.

4.2 Procurement of Services

4.2.1 Procurement of Contractual Services in Superfund for Remedial Program

In the SFD, contracts are used to obtain technical services to be used within the Superfund and "buy-ins" from other Regions or Divisions on a limited basis. Contracts are awarded according to the Federal Acquisition Regulations (FAR) Section 13 and the EPA Contracts Management Manual. Together, these documents establish government-wide policies and procedures governing the acquisition process.

Contracts specific to Superfund Remedial Action include the Remedial Action Contracts (RACs), Enforcement Support Services (ESS), and the Regional Oversight Contracts (ROC). The responsibility for administering these contracts rests with the RPMs, POs, Contract Specialists (CSs) and Contracting Officers (COs). To serve on these contracts, the above individuals must meet the qualifications outlined in Chapter 7 of the EPA Contracts Management Manual. These qualifications include the required training, experience, and workload limitations.

To access these contracts, the RPMs must identify through a Statement of Work (SOW) the specific services/support they are seeking. The individual SOWs must be written according to the overall provisions of each contract and must be accompanied by an Action Memo and an Independent Government Cost Estimate (IGCE). To fund the services, the RPMs are asked to plan and document their financial needs in the Superfund Comprehensive Accomplishments Plan (SCAP). This planning helps to ensure that funding requests are identified and available when needed. All procurements are documented using the procurement request form (EPA Form 1900-8) which is available on the LAN computer network. Together these documents constitute a funding package.

Funding packages are reviewed by the RPMs, POs, and Superfund management for completeness and accuracy. The funding package is then forwarded to Budget where the Procurement Request is assigned a document control number (DCN). The package is subsequently sent to CO who is the sole individual authorized to procure contractual services on behalf of U.S. EPA. The Federal Government is not bound by any commitments made by other than the CO.

Once the funds and services are procured, it is primarily the responsibility of the RPMs, and POs, to monitor the individual work assignments issued under the umbrella contract to ensure that the government is receiving quality service at a reasonable cost. This is accomplished, in part, through:

1) review and documentation of the monthly progress reports and invoices;
2) a required QAPP for sampling and
3) biannual contractor performance evaluations.

For monitoring the remedial contracts in Superfund, the Division requires the RPMs to complete a "2-way memo" as a way of documenting the reasonableness of costs and technical quality of the work based on their review of the contractor's monthly invoice and monthly progress report. The invoices and monthly progress reports are also reviewed by the POs for completeness, reasonableness and accuracy.

To ensure the quality of sampling activities undertaken either by the remedial contractors or the PRPs, EPA requires that all sampling be conducted in accordance with the EPA approved QAPP.

The remedial contractors are evaluated biannually. This gives the RPMs and the POs the

opportunity to document the technical quality of the contractor's services as well as its timeliness and costs.

All program personnel must be aware of "personal services" which are characterized by an employer-employee relationship between government and contractor employees. These contracts are illegal in EPA. Personnel services conflicts arise when government employees assume the right to instruct, supervise, or control a contractor's employee in how he or she performs work. It is the contractor's right to hire and terminate, to assign, and to organize and implement tasks as the contracting organization deems appropriate. The program may tell the contractor what to do within the terms and agreements of the contract, but not how to do it.

4.2.2 Procurement of Contractual Services in Superfund for Removal Program

In the SFD, contracts are used to obtain technical services to be used within the Superfund and "buy-ins" from other Regions or Divisions on a limited basis. Contracts are awarded according to the Federal Acquisition Regulations (FAR) Section 13 and two EPA documents: EPA 1900-Contract Management Manual and the EPA Acquisition Regulation Manual (EPAAR). Together, these documents establish government-wide policies and procedures governing the acquisition process, including the prohibition of services which are of a policy and decision-making nature that they should remain the sole authority of EPA.

Contracts specific Response Action Contracts include START and Emergency Rapid Response Services (ERRS) Contracts.

The responsibility for administering these contracts rests with the Task Monitors (TMs), OSCs, Work Assignment Managers (WAMs), RPMs, POs, CSs and COs. To serve on these contracts, the above individuals must meet the qualifications outlined in Chapter 7 of the EPA Contracts Manual (EPA-1900). These qualifications include the required training, experience, and workload limitations.

START

For the START contract, the TM must provide the PO with a SOW and an estimate of the effort required. This SOW must be in conformance with the START contract SOW. The START contract is bulk funded for the removal program. Other programs wishing to use START resources may buy-in to the contract if the work required falls within the contract scope. The TMs are usually on the site with the START members and monitor contractor performance daily. The TMs review START monthly progress reports on a monthly basis and complete a two-way memo to the PO documenting contractor performance. TMs may also participate in the weekly START meeting. This meeting is held to discuss schedules, budgets, and any pending issues.

ERRS

The ERB Branch Chief must approve all ERRS funding requests. OSC's will request ERRS funding through their Section Chief. The ERRS PO will then be notified when the funding request is approved. The OSC must forward to the ERRS PO a SOW, the action memo, and a detailed cost estimate. The PO will than prepare a Task Order. The OSC must be on-site to monitor the contractor during periods of significant cleanup activity including all hot zone work, emergency responses, transportation and disposal and public relations activities. Daily work orders are prepared by the OSC and signed daily by the OSC and the Response Manager. Costs are monitored daily.

All of the removal contracts performances are reviewed annually and entered into the National Institutes of Health Contractor Performance System. For non emergency funding requests, the Enforcement Specialist must concur that all reasonable enforcement activities have been performed.

All program personnel must be aware of "personal services" which are characterized by an employer-employee relationship between government and contractor employees. These services are prohibited at EPA. Personnel services conflicts arise when government employees assume the right to instruct, supervise, or control a contractor's employee in how he or she performs work. It is the contractor's right to hire and terminate, to assign, and to organize and implement tasks as the contracting organization deems appropriate. The program may tell the contractor what to do within the terms and agreements of the contract, but not how to do it.

4.2.3 Assistance Agreements

Assistance agreements are used when both parties (EPA and the group providing the assistance) derive benefit out of the service. This usually occurs with contracts or cooperative agreements with states and Indian tribes and with interagency agreements with other federal agencies. QA requirements are developed for all assistance agreements including environment data collection activities.

SFD follows the requirements of 40 CFR Part 35 Subpart O - Cooperative Agreements and Superfund State Contracts for Superfund State Contracts for Superfund Response Actions. SOWs for assistance agreement are usually developed jointly by the Division's Project Manager and the assistance recipient. Once the SOW is completed, the parties must agree on the quality standards for assuring the product or services. It is the responsibility of the Project Officer to be knowledgeable of EPA QA policy and to represent these standards during development of the projects SOW.

Special conditions are usually included in assistance agreements. The project officer will list the conditions for which project participants must adhere. One of these conditions relates to QA project plans. The special conditions for pre-remedial activities are contained in 40 CFR Part 35.6055(b)(2). The special conditions for remedial activities are contained in 40 CFR Part 35.6105(a)(2)(vi).

These conditions require that participants must meet the requirements of 40 CFR Part 31.45 (quality assurance) and have an EPA approved QAPP in place before beginning field work.

5.0 DOCUMENTATION AND RECORDS

Managing recorded information is an important responsibility of every Federal agency. It is the basic administrative tool by which the Government does its work. Like other resources, they must be managed properly for the agency to function effectively and comply with Federal laws and regulations. According to Federal law (44 U.S.C.2901), records management means:

The managerial activities involved with respect to records creation, records maintenance and use, and records disposition in order to achieve adequate and proper documentation of the policies and transactions of the Federal Government and effective and economical management of agency operations.

Agency record keeping requirements apply to both the creation and maintenance of records as set forth in the National Archives and Records Administration (NARA) Regulations (36 CFR Part

1222).

5.1 Document Control

The SFD has a centralized facility for the secure storage, maintenance, retrieval and circulation of Superfund documents. Records are stored at this facility to provide consistency in the way the agency site related records are managed, provide greater efficiency in the filing and retrieving of these documents, increase security, comply with NARA disposition schedules, and improve utilization of available space. This facility is staffed through a record management contract (RMSS). Procedures for assuring the adherence to these regulations is contained in "The Superfund Procedures Manual." This manual is updated on a quarterly basis by the Superfund Record Officer.

The SFD has designated a full-time Records Officer (RO) who is responsible for the maintenance of the SFD Record Center and its holdings. The RO is also responsible for the control of Confidential Business Information (CBI) and acts as the Document Control Officer (DCO). The SFD has also named an Assistant Records Officer/Assistant DCO who functions as the back up in the Records Center to assist the RO in monitoring the contract staff and providing technical direction. The RO and Assistant RO are responsible for the following:

♢ Provide training to SFD personnel on the procedures for the use of the record center.

♢ Coordinate the development of the Administrative Record (AR) for Superfund sites.

♢ Work with SFD contract staff for retention of PO files.

♢ Maintain work performance documentations for future cost recovery.

♢ Provide yearly training on CBI and AR regulations.

It is ultimately the responsibility of the RPM/OSC to file all sites related documents in the record center; however, procedures have been developed to have outside contractors send closed work assignments directly to the Records Officer in the record center. This procedure captures all documents pertaining to a site, and allows the records center staff to control duplication of documentation.

5.2 Document Preparation, Review, and Approval

Procedures to be used for document preparation, review and approval will depend upon the type of document. For example, an internal document will have different preparation, review, and approval requirements than an external document. Document procedures will be determined by the task lead and immediate supervisor.

The correspondent files and records pertaining to QAPP/Data Validation reviews, including the QA Document Tracking System and the quarterly reports providing the status of documents submitted for the review to FSS are maintained in the FSS.

6.0 COMPUTER HARDWARE AND SOFTWARE

The Division periodically conducts analysis on computer hardware needs. The analysis- includes (but are not limited to) interviews with major database users, evaluation of present hardware,

evaluation of new hardware, and communication with the Information Technology Section (ITS), RMD, about changes in Regional hardware, systems or IRM standards that would impact the SFD. A needs' analysis is usually conducted by the Division's PC-Division/Office Coordinator (PC-DOC) in conjunction with the Program Management and Information Section (PMIS), which has responsibility for the program's major databases.

Changes to computer hardware are usually made on an annual basis due to the structure of the budget cycle. The PC-DOC is responsible for purchasing all new computers (with a few minor exceptions). By having all computer hardware purchases funneled through a single point, the PC-DOC, the Division ensures that only the most appropriate equipment is purchased.

PMIS is responsible for the Division's software development, which include the development of internal applications to meet specific user needs. PMIS staff work very closely with requesters to ensure that the application being developed is workable and meets the requestor's needs. The software developers are responsible for developing all documentation for their applications, maintaining them over time through fixes, updates, etc., and periodically reviewing the software's applicability with the requestor.

Commercial software is evaluated by the requester or by the PC-DOC. A requestor can specify software based on their own analyses and needs. Also, the PC-DOC will evaluate user needs and purchase commercial software to meet those needs. In both cases a need's analysis is conducted first, then different types, brands or versions of commercial software are evaluated to determine how well they meet those needs.

Meeting the IRM requirements pertaining to national databases and applications are the responsibilities of the National Superfund Office, since they are responsible for developing such applications. IRM requirements that pertain to the Division data and information are maintained by the ITS, RMD. The ITS has the regional responsibility for meeting IRM standards. ITS works in collaboration with the Superfund PC-DOC to ensure that software developed in-house meets the necessary standards, and that data management practices and procedures follow IRM guidelines.

7.0 PLANNING

It is SFD policy that activities for collecting of environmentally related data are planned effectively. Quality planning must occur at different levels to ensure that data meets the SFD programmatic and quality goals:

- ♢ Program Specific
- ♢ Project Specific

7.1 Program Specific

Superfund Divisional Programs covered by this management plan are:

- ♢ Remedial Program
- ♢ Removal Program (Emergency Response, Site Assessment and Brownfields)

Developing DQOs when initiating a new program or incorporating major changes is a mandatory component of QA planning at the program level. DQOs at the program level include all sources of error (e.g., design, sampling, measurement, or indicator error) that will accumulate and affect the interpretation of Superfund data. Program level DQOs are defined by their ability to meet

SFD program objectives discussed with desired certainty (allowable total error). As discussed in Section 2.3, the acceptable probability of all sources of error established by decision makers are the DQOs. Data Quality Objectives are used as performance criteria for assessment of data quality for their adequacy in determining status and trends. The following documents are used for the implementation of the DQO process for Superfund sites: "Data Quality Objectives Process for Superfund" EPA 540-R-93-071, September 1993 and "Guidance for the Data Quality Objectives Process " EPA QA/G-4, August 2000.

It is critical to include this QAMP as part of the planning when modifying existing programs or designing new programs. Although this QAMP outlines the minimum QA requirements for Superfund programs, it is likely that some of the programs covered by this QAMP may need more QA specificity and detail for implementing their programs. In that case, supplemental QA components should be developed as an addendum to this QAMP. This addendum will be included as appendices in future revisions of this QAMP.

It is responsibility of senior management in the program to ensure that line managers evaluate the need to include statisticians in the network design stage.

The work plan should outline QA activities for the upcoming year, including budget information.

7.2 Project Level Planning

A project is an organized set of activities within a program. The planning process will identify the project staff including the designated project manager who will guide the planning activities. The designated project manager will identify all participants involved in or related to the planning activity. The planning process will include developing a description of the project goal, objectives, and questions and issues to be addressed by the project. The QAPP is a primary vehicle for documenting the required level of data quality for the project. Section 2.4 describes the process used to develop and prepare a QAPP; QAPP planning documentation should identify the personnel responsible for all components of the QAPP described there. Remedial Project Managers (RPMs) will be responsible for the development of these components. As part of the project planning, RPMs will develop schedules for development, review and completion of required documentation, including adherence to the Agency policy of peer review. Appropriate reviewers of the documentation should be identified.

The QA Team Leader, with assistance from QA staff, will be included in the project planning process, and will assist RPM/PM to determine the need of statistical assistance. The QA staffs will review the draft project QAPP. Section 2.4.1 describes in detail a review and approval process. QA practices being used should be reflected as a well-defined activity in each project plan involving the collection or use of environmental data.

Project level planning utilizes Systematic planning process or DQO process address concepts of customer satisfaction and acceptance decision uncertainty, respectively. Systematic planning process is used in Superfund projects to answer, as follows, project planning questions:

◊ ***What is the problem and how does it relate to the Superfund Mission?***

Verbal statements of the general problem should be narrowed into succinct questions that are unambiguous and can be answered with specific data.

◊ ***Once the questions are defined, what are the variables that answer the questions?***

This process tries to define the smallest set of variables necessary to answer the specific questions raised in the first step. Then, these variables can be assembled into precise project objectives that illustrate how the variables will be measured and combined to answer the questions.

◊ ***What is the allowable level of uncertainty permitted that still enables the questions to be answered?***

This step is necessary for the development of sampling design (i.e., where to sample, how many samples to collect, methods of analysis, etc.) and for the development of QA project requirements to reduce the uncertainty to allowable limits.

◊ ***Who are the customers and what are their expectations?***

The customers that will utilize the information must be identified. The plan must identify what types of information are needed (e.g., summary information, detailed trends, graphs, geographic information system (GIS), etc.). This information will assist the project leaders in focusing the project objectives, as well as determining the necessary data quality.

◊ ***Who are the suppliers and what are their responsibilities?***

Details on the organizations participating in the project and their responsibilities are required to ensure that important phases and operations of the program are not overlooked. Project phases should include: management, design, implementation, methods development, planning and budget, information management, reporting, and QA.

In developing QAPPs and DQOs for various projects, SFD managers should understand that each data collection activity must produce statistical valid data in order to meet both program and project-level objectives. During the planning stage of a project, the RPM should include a statistician to help planners determine how the measurement data will be used to answer the project's questions. Various design scenarios can be developed to assist planners in utilizing their resources in the most efficient manner, while maintaining an adequate level of data quality.

8.0 IMPLEMENTATION OF WORK PROCESS

8.1 Program Implementation

All programs that collect environmentally related data shall document their QA procedures and develop appropriate SOPs for their program.

All SOPs shall be documented in writing and made accessible to all persons involved in the implementation of the program. If SOP or written documentation of those SOPs do not exist for a particular program, it is the responsibility of the management of that program to ensure that needed SOPs are developed and made available to program staff.

Where the program uses data generated by others, it must develop criteria and process with which to evaluate the acceptability of the data supplied. This ensures that the data fit within the margin of error constraints, as established by EPA program management.

8.2 Project Level Implementation

The Workplan and quality products outlined in the QAPP will be implemented as approved. Any changes to the QAPP will be documented and the QAPP amended. Any amendments to the

QAPP will need to be reviewed and approved by the RPM and QA staff as appropriate. The project time line should include specific target dates for QA/QC products (e.g., QAPP development, auditing time-lines) so that progress and completion of the QA/QC activities can be tracked.

To ensure the quality of sampling activities undertaken either by the remedial/removal contractors or the PRPs, EPA requires that all sampling be conducted in accordance with an EPA approved QAPP. (See Sections 2.3.1 and 2.3.2 of the document for the QAPP approval process in Superfund Division.)

The completed signature page should be submitted to FSS after all signatures are collected. The dates on the signature page will be the entered as QAPP approval date in FSS data files.

The information from the QAPP review request form along with the QAPP approval date is entered into a computer data base maintained by FSS. All SFD supervisors have access to the data base to be able to check on status of QAPP approval.

Site assessment work is also performed by Region 5 states and Remedial Action Contract (RAC) contractors. A generic QAPP has been developed by each of these separate entities, and has been approved. Site assessment work performed by the START contractor will be conducted under the START generic QAPP. Site specific sampling plans are prepared for each site sampled by the state and RAC contractors.

Managers and QA reviewers are responsible for ensuring that specific requirements of reports on the QA products are included in every work assignment and task delivery order that involves environmentally related data collection.

9.0 ASSESSMENT AND RESPONSE

An assessment is a formal evaluation of performance to predetermined standards, and documentation of audit results to effect change toward improved performance. Audits are the principal means used by EPA to determine compliance and to control systems in a real-time manner to improve performance. EPA defines, and uses, five types of audit/assessment tools: (1) technical system audits (TSA); (2) performance evaluation (PE); (3) management system review (MSR); (4) audits of data quality (ADQ); and (5) Data Quality Assessment (DQA). The mechanisms to be used for these assessments are summarized below.

9.1 Annual Review of the Quality Assurance Management Plan

The QA procedures described in the QAMP will be assessed annually and updated as necessary. The Quality Assurance Team leader will be responsible for coordinating this effort and ensuring that appropriate changes are incorporated into the QAMP. Each manager will be responsible for ensuring that appropriate staff participate in the review of the Division-wide QA program as well as reviewing any addenda to the QAMP. The program-specific changes will be provided to the QA Team leader for incorporation into QAMP. All Branch Chiefs, the Associate Division Director and the Division Director will review and approve changes to the QAMP before their submittal to RQAM. The annual review of the QAMP will be undertaken at the same time as the development of the Divisional Work Plan.

9.2 Audits and Assessment

Internal and external audits and assessment will be the principal means for determining compliance

with and effectiveness of the QA control system defined in the SFD QAMP. Internal audits and assessment are conducted by the SFD staff. External audits and assessment are conducted by RQAC or SFD contractors. Internal audits and assessment should be conducted by teams of QA and technical staff at frequencies sufficient to ensure that appropriate QA measures are being implemented. External audits are conducted by an outside organization at the request of SFD management. If auditing resources are limited, an environmental data collection program or activities that are highly visible or those produce results used in rule making, policy decisions, or to support litigation will be given priority.

Senior managers from each Branch, with assistance from QA Team Leader, are responsible for establishing audit procedures to meet the specialized needs of its program. Audits of the SFD programs and activities are to be conducted in accordance with preestablished protocols.

9.2.1 Technical System Audits (TSA)

TSA is a thorough, systematic on-site qualitative inspection of facilities, equipment, personnel, training, procedures, record-keeping, quality control practice and data validation, data management, and reporting aspects of field and laboratory activities**.**

The TSAs are performed prior to the data collection activities in order to verify the existence, and to evaluate the adequacy of equipment, facilities, supplies, personnel, and procedures that have been documented in the QAPPs. Additional system audits (e.g., field audits of sample collections, laboratory analysis, etc.) may be conducted during the data collection activity as needed. The FSS will conduct the field audits for states and for the RAC contractors using a review check list. The SFD SOP will be followed for submitting the PE samples to the laboratories and for data validation of the PE sample results. For CLP laboratory audits CLP protocols will be followed.

TSAs will be requested by the RPMs at the time the draft QAPP for the project has been developed and written. The TSA request will be made to the QA Team Leader and will include information such as the nature of the project, the project needs (e.g., the type of monitoring activity, monitoring parameters, procedures to be used, etc.). The QAPP serves as the benchmark for the audit. The respective program QA staff will be responsible for conducting the audits, and documenting the audit results.

9.2.2 Performance Evaluation (PE)

A PE is defined as the incorporation of a calibrated device traceable to a known reference standard (i.e., use of samples of known composition and concentration) randomly into the measurement system to check the analytical procedure. These samples are used to control and evaluate the accuracy and precision of the measurement systems, and to determine whether the established QA objectives of the project have been met. These samples can be introduced into the measurement system as single blind (the composition is known, but concentration is not) or as double blind (both composition and concentration are unknown).

The RPM shall make the request, through the SFD QA Team Leader**,** for a PE when the draft QAPP for the project has been developed and written. The PE request shall identify the monitoring parameters, analytical methods/procedures to be used, the required detection limits, and the facility (i.e., name and address of the laboratory) that will provide the analytical services. PE of the laboratory for approval/disapproval shall be performed prior to the initiation of the data collection activity. The respective program QA person will schedule the evaluation. The QAPP will serve as the benchmark for survey officer to determine what evaluation materials are to be used. The frequency of evaluation shall be determined based on the needs, past experience with a

particular sampling and analysis procedures and Agency guidelines, and past performance of a particular laboratory.

9.2.3 Management System Review (MSR)

An MSR is an on-site evaluation to assess the organization's internal management structure and its documents to determine whether the organization is implementing a satisfactory QA program. It is used to determine the effectiveness of, and adherence to the QA program, and the adequacy of resources and personnel provided to achieve the required data quality.

An MSR of the QA program will include reviews, at a minimum, the implementation of the following items:

- ♢ An assessment of the overall effectiveness of the QA management system, as measured by its adherence to the approved QAMP.
- ♢ Project planning procedures including the use of DQO development process.
- ♢ Procedures for QA project plan development, preparation, review and approval.
- ♢ Procedures for developing and approval of standard operating procedures (SOPs).
- ♢ Procedures for conducting internal audits.
- ♢ Responsibilities and authorities of the various line managers and the quality assurance program manager for carrying out the QA program.
- ♢ The degree of management support
- ♢ Procedures for document control and records keeping.
- ♢ Tracking systems for assuring the implemented QA program is operating, and the corrective actions to the deficiencies uncovered during the audits have been properly taken.

Internal MSR within SFD is conducted by the SFD QA Team Leader and QA staff. The internal SFD MSR will be conducted at a rate of at least one SFD program element (e.g., Remedial or Removal program) per year such that all SFD program elements have been reviewed within a 3-year cycle. Both positive and negative finding will be used in the preparation of the MSR report. The appropriate managers should respond in writing letter including the corrective action for identified deficiencies and approximate implementation dates.

External MSR of the SFD and other Region 5 media programs are the responsibility of the Regional QA Manager and the Regional QA Core. The external MSRs will be conducted at a rate of at least one Division per year such that all Region 5 media programs have been reviewed within a 5-year cycle.

MSR of Region 5 are the responsibility of Office of Environmental Information Quality Assurance Staff. MSR of Region 5 will be based upon the current approved Region 5 QAMP as well as Divisional QAMPs.

General guidance used by USEPA for conducting MSRs is presented in the Quality Assurance Division document "Guidance for Preparing, Conducting and Reporting the Results of Management System Reviews" EPA QA/G-3 (January 1994 Draft).

9.2.4 Data Quality Assessment (DQA)

The Data Quality Assessment process includes both the qualitative review of the project to determine if project-specific QA/QC practices are followed and project objectives are achieved, and the statistical analysis of data to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality. A complete or partial DQA process can be performed during the assessment phase of data life cycle, which includes the planning, the implementation and the assessment phases. DQA is used to determine if the planning objectives were achieved. See Section 2.6 for the details. During the DQA, the data is first validated and verified to ensure that the sampling and analysis protocols specified in the QAPP were followed, and that measurement systems performed in accordance with the criteria specified in the QAPP. Then the validated data is reviewed to determine if the quality of the data is satisfactory.

DQAs will be conducted and utilized on project by project basis. The results of the DQA should be used for two specific purposes. First, for the specific decision, it can be used in making recommendations to the decision maker to modify portions of DQAs. Secondly, it can be used as a guide for the planning and acquisition of supplemental data for the project.

The DQA process involves three major areas that begin with a review of the planning documentation and end with the answers to the questions posed during the planning phase of the study:

1. **Project implementation**: Evaluate the following:

♢ Field activities: Chain-of-Custody; holding times; number of samples and QC samples collected; number of locations sampled; method used for collection; approved procedures used; measurement conducted; and field data validation conducted,

♢ Laboratory analysis: parameters reported; holding times; approved procedures used; and data validation conducted,

♢ Others: field inspection conducted; PE samples analyzed and reported; independent validation performed; corrective actions appropriately implemented for both field and laboratory activities

2. **Conformance to approved performance criteria**: Evaluate the field and laboratory data through reviewing the data sets to determine the conformance to the requirements specified in the approved QAPPs. RPMs/OSCs are responsible for initiating the data review/validation request to the respective program QA personnel. Data will be assessed in terms of its: precision, accuracy, representativeness, completeness, comparability (PARCC).

3. **Achievement of project objectives:** Evaluates the following:

♢ Specific objectives are met;

♢ The overall project objectives are met

- Data adequacy is sufficient for overall project objectives (i.e., valid conclusion can be made)

- Regulatory decision can be made

♢ The overall project objectives are achieved

- Data support original assumptions/hypothesis

- Data indicate the needs of establishing new assumption/hypothesis

QAD's guidance titled "Guidance for Data Quality Assessment", EPA QA/G-9, 2000 and the "Data Quality Evaluation Statistical Tools", EPA QA/G-9D, 1996 (or DataQUEST software program) will be used as a guide.

10. QUALITY IMPROVEMENT

The intent of this QAMP is to provide the basis for integrating appropriate QA activities in a full cycle of Superfund Division programs from planning phases through the evaluation phases. If the principles outlined in the QAMP are followed, problems can be detected in a timely manner, before programmatic and financial issues become critical and hinder program implementation and decision making.

10.1 Program Review

The QAMP details SFD's guidance for the areas covered in each section of the document. Many sections include actions that would lead to the improvement of quality. The document will be approved by SFD Director, Associate Division Director and all Branch chiefs, thereby demonstrating their commitment to the QAMP. It is the responsibility of management and SFD QA Team Leader to ensure that SFD staffs follow the guidelines of QAMP. Superfund Division management will be responsible for identifying planning, implementing and evaluating the effectiveness of quality improvement activities at the program level.

Annually the QAMP will be reviewed by the SFD QA Team leader and management and modified, if needed, to reflect changing needs or additional guidance. Revisions will be noted by the change in revision number and date of the revision included in the header information and table of contents. All revisions will be distributed to each program for review/comment before implementation.

10.2 Project Reviews

It is SFD policy that the RPMs, with assistance from QA staff and other technical support staff, review project implementation at regular intervals to identify where improvements in data quality can occur. The project specific correction actions should be described in the details in Group C, section B of the site specific QAPP.

Project reviews may be conducted by using the following tools:

- ♢ Technical audits;
- ♢ Data Quality Assessments;
- ♢ Peer reviews;
- ♢ Conference calls
- ♢ Meetings

It is suggested that a "wrap-up" meeting occur at the end of each data collection activity. Report on a preliminary audit of Data Quality should be made available for this meeting so participants can determine whether the QAPP was followed and data quality was controlled to an acceptable level. Weakness, problems and recommended corrective actions should be documented in the QA section of the final project report for future Superfund sites.

10.3 Peer Review

Region Order RV 2150.1 was issued on October 5, 2000, to assure the high quality of scientific and technical work products issued by Region 5. The Order addressed the requirements of the EPA Science Policy Council Peer Review Handbook to ensure that peer review of work products is properly and consistently performed, that each decision as to whether to conduct a peer review is properly documented, that documentation produced during the peer review process, records of approval for final reports, final reports, and supporting data are obtained in the appropriate manner and for the appropriate time, and that release or publication or Regional work products that have been peer reviewed is authorized by appropriate decision maker. The Superfund Division will fully implement Regional Order RV 2150.1. The Superfund Division Director serves as the decision maker for peer review. The Field Services Section Chief is the SFD peer review coordinator.

ATTACHMENT A

Field Services Section

SOP for QAPP and Removal SAP log-in and log out

1. Pre-QAPP Meetings

   The information about the meeting (notes, etc.) should be inserted in the correspondence files with other site information. For a new site the person attending the pre-QAPP meeting is responsible for starting a new file (which includes the correspondence file folder).

2. Log-in and log out of the QAPPs, QAPP revisions, SOPs, and PRPs data validations received for review by FSS chemists.

   a. *The document was sent to FSS Section Chief.* Section Chief/QA Team Leader will assign the SF log-in number and the document will be given to the chemist for review with status report form attached.

   b. *The document was sent to the reviewer.* The reviewer is responsible for informing the Section chief or QA Team Leader about newly received revised document. The SF log-in number will be assigned. It should be done immediately after receipt of the document.

   c. *If the document was sent for the review without the QAPP Review Request form*, this form will be sent electronically from G:\SHARE\MODELS\QAPP\ FORMS\ QAPPREV.REQ to RPM with request to fill this form. The QAPP will not be log-in and review will not start until the information will be provided.

   d. Removal SAPs will not be reviewed but only added to an internal data base for reporting purposes.

3. After the review finished the following should be done:

   1. The status report form should be filled. Attaching the comments is optional.

   2. Copy of the comments/approval should be put in a correspondence file (brown folder)

   3. Electronic copy and hard copy (with critique form) of the comments should be sent to the RPM.

   4. All documents used for review (QAPP, Work Plan, FSP) should be sent back to the RPM. FSS should keep only correspondence files.

Superfund Division Requirements for the Emergency Response Branch Site-Specific Sampling and Analysis Plans

1. Site Description
2. The locations of sample collection (maps)
3. Any climatic limits on sampling
4. Number of samples collected for each matrix (soil, drums water, etc.)
5. Number and size of the containers
6. Number of Quality Control Samples (blanks, duplicates, etc.) collected for each matrix
7. Field and Laboratory analytical methods used for analysis
8. The acceptable level for data decision should be specified in the SAP
9. Who is in charge (for PRP projects)
10. Signature page with signatures: OSC, PRP, contractor's QA staff overseeing sampling, on-site lab QA, and off-site QA if applicable.

REGION 5
PRE-AWARD QUALITY ASSURANCE REVIEW FORM
FOR SOLICITATIONS AND CONTRACTS
(Attach the Draft SOW)

I. GENERAL INFORMATION

Descriptive and/or Contract Title: _____

Sponsoring Program Office: _____

Approximate Dollar Amount of Contract: _____

Duration of Contract: _____

II. ENVIRONMENTALLY - RELATED MEASUREMENTS

Does this contract require environmentally-related measurements ? (See instructions for definition and examples)

_____(YES) Complete the rest of this form (Parts III, IV and V);

_____(NO) Go to Part V (Do not complete Parts III & IV), sign and submit with the procurement request (PR) or procurement initiation notice (PIN).

III. ALLOCATION OF CONTRACT COSTS

_____ % Estimated percentage of contract costs allocated to environmentally-related measurements.

Yes (Y) or No (N):

_____ Is Quality Assurance (QA) specifically included in the technical evaluation criteria?

_____ Are contract costs associated with QA to be proportionate to the percentage of costs allocated to environmentally-related measurements?

IV. QUALITY ASSURANCE REQUIREMENTS:

Document required? *Y or N*	**Type of Document**	**When due?** *With Proposal - P* *After Award - A* *With work assignment - WA* *During work assignment - D*
	Quality Management Plan (QMP)	
	Quality Assurance Project Plan (QAPP) for: ☐ ***the entire contract***, ☐ ***each applicable project***	
	Programmatic Quality Assurance Project Plan	
	Project-specific supplement to Programmatic Quality Assurance Project Plan for each applicable project	
	Combined Quality Management Plan/Quality Assurance Project Plan	
	Other documentation or requirements specified by Divisional QA Manager/ Coordinator:	
	A. Quality system assessment	
	B. Laboratory and/or field audits	
	C. QA Reports	
	D. Other:	
	E. Other:	

V. CONCURRENCES

The following signatures verify that QA requirements appropriate for this solicitation have been established (Parts III and IV completed) or no environmentally-related measurements are included in this solicitation (selecting "No" in Part II):

_____ _____

Divisional QA Manager/Coordinator **Date**

_____ _____

Project Officer **Date**

REGION 5
POST - AWARD QUALITY ASSURANCE REVIEW FORM
FOR WORK ASSIGNMENTS, DELIVERY ORDERS AND TASK ORDERS
(Attach the Draft SOW)

I. GENERAL INFORMATION

Contract Title: _____

Contract Number: _____

Work Assignment Program Office: _____

II. ENVIRONMENTALLY - RELATED MEASUREMENTS

Does this Work Assignment (WA)/ Delivery Order (DO)/ Task Order (TO) require environmentally - related measurements? (See instructions for definition and examples)

_____(YES) Complete the rest of the form (Parts III and IV);

_____(NO) Go to Part IV (Do not complete Part III), sign and submit with the WA, DO or TO.

III. QUALITY ASSURANCE REQUIREMENTS

Document required? *Y or N*	**Type of Document**	***When due and/or frequency?** *(Examples: 90 days from contract award; 60 days after receipt of work assignment; by 15th of each month; with WA report)*
	Quality Management Plan (QMP)	
	Quality Assurance Project Plan (QAPP) for: ☐ ***the entire contract***, ☐ ***each applicable project***	
	Programmatic Quality Assurance Project Plan	
	Project-specific supplement to Programmatic Quality Assurance Project Plan for each applicable project	
	Combined Quality Management Plan/ Quality Assurance Project Plan	
Document required? **Y or N**	**Type of Document**	**When due and/or frequency?** *(Examples: 90 days from contract award; 60 days after receipt of work assignment; by 15th of each month; with WA report)*

	Other Documentation or requirements specified by Divisional QA Manager/ Coordinator:	
	A. Quality System Assessments	
	B. QA Reports: ☐ Interim Report ☐ Final Report	
	C. Field Audits	
	D. Laboratory Audits	
	E. Other:	
	F. Other:	

IV. CONCURRENCES

The following signatures verify that the QA requirements appropriate for this WA, DO or TO have been established (Part III completed above) or no environmentally-related measurements are included in this WA, DO or TO.

WA Manager, DO Project Officer or TO Project Officer — **Date**

Divisional QA Manager/Coordinator — **Date**

Project Officer — **Date**

ATTACHMENT B